Protocol

Remote patient education for people living with an ostomy: a protocol for an Italian consensus of experts

ABSTRACT

Aim/Hypothesis People living with an ostomy face physical, psychological, and social challenges that benefit from structured education pathways. While in-person education conducted by stomatherapists improves outcomes, ostomy-specific guidance for remote education is lacking. This study aims to develop a national, expert-validated set of indications specifying what to teach, how to deliver it remotely (including mixed pathways), and how to evaluate it.

Methods A modified Delphi, coupled with a consensus conference approach, will be conducted and reported via ACCORD. A heterogeneous national panel of stomatherapists with at least five years of professional experience and who have attended a 1500-hour specialisation course in stoma care; and expert patients, identified through the Italian National Federation of the Association of Incontinence and Ostomy Patients, will be recruited. Round 1 will be a 90-minute online focus group discussion to refine literature-derived indications and key definitions. Subsequent rounds, based on online surveys, will rate statements on a 4-point scale, allowing for free-text comments and controlled feedback. Consensus is defined as ≥75% agreement, with a target of ≥70% response rates between rounds. Quantitative data will be analysed for percentages and rates; qualitative comments will guide iterative revision.

Results Outputs will include core educational content; criteria distinguishing face-to-face, remote, and mixed pathways; and minimum standards for equity, privacy, consent and data protection.

Conclusion The study will deliver the first national consensus of experts for remote ostomy education, offering a practical, person-centered, secure blueprint for routine services and a shared outcome set for quality improvement.

Keywords consensus, Delphi technique, education, ostomy, remote education.

For referencing Villa G, et al. Remote patient education for people living with an ostomy: a protocol for an Italian consensus of experts. WCET™ Journal. 2026;46(1):26-30.

DOI https://doi.org/10.33235/wcet.46.1.26-30

INTRODUCTION

Living with a stoma involves navigating a complex, multifaceted journey marked by physical, psychological, and social challenges.[1–3] The surgical creation of a stoma not only modifies bodily function but also impacts body image, emotional well-being, social participation and overall quality of life.[4,5] Consequently, providing tailored, structured and timely patient education is essential. Ideally, such educational interventions should start in the preoperative phase and continue postoperatively, helping patients adapt to their new reality and fostering autonomy in self-care.[6] The World Health Organization (WHO) has long recognised the importance of patient education in enabling individuals to manage their health effectively. Its 1998 and 2023 reports underscored the necessity of person-centered, accessible, and continuous educational programs to enhance self-management, particularly in chronic conditions and long-term care conditions.[7,8] In the context of stoma care, these guidelines have been translated into structured educational pathways that incorporate a range of methods, including printed booklets, face-to-face teaching, demonstrations, role-playing, and ongoing support. These multimodal approaches have been shown to enhance knowledge, coping strategies,

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and adherence to care routines.[9,10] Currently, these educational interventions are primarily delivered by specialised nurses known as stomatherapists, who possess advanced clinical and educational competencies in stoma management. Numerous studies have demonstrated that education provided by stomatherapists leads to improved outcomes in terms of self-efficacy, self-monitoring, independence in stoma care and health-related quality of life.[9,11] However, despite the effectiveness of in-person education, the increasing availability of digital tools and the necessity to maintain continuity of care during the COVID-19 pandemic have accelerated the adoption of remote educational modalities, such as online platforms, video consultations and telehealth services.[12] While these digital tools offer new opportunities for education and support, their implementation in stoma care remains fragmented and lacks standardised guidance. Nowadays, there are no clinical guidelines or evidence-based recommendations that define how remote educational interventions should be structured, delivered or evaluated in this specific population. In an ideal scenario, clinical guidelines would be informed by robust empirical evidence. However, in areas such as remote patient education for individuals living with a stoma, the literature remains insufficient, and best practices are yet to be established.[13] In the absence of a strong evidence base, consensus-based methodologies, such as the Delphi technique are recommended for identifying key components and criteria for practice. The Delphi study is particularly well-suited for areas where expert opinion is needed to guide decision-making and where empirical evidence is either lacking or emergent.[14]

Aim

The objective of this Consensus of Experts will be to aggregate expert judgments and to assess the consistency of responses across successive rounds to achieve consensus on the conduct and implementation of remote patient education pathways for individuals living with an ostomy. This Delphi study will be applied at a national level in Italy.

METHODS

A modified Delphi study will be conducted in conjunction with a consensus conference approach.[15,16] The process will involve administering multiple rounds of surveys to a national panel of experts. In the first phase, a focus group discussion will solicit the panel's opinions on remote patient education for people living with an ostomy. The research team will analyse these responses and return them to the panel as statements or questions. In the subsequent questionnaire, experts will be asked to rate or rank these statements according to their expertise. This iterative process will continue until consensus is achieved on some or all items, as needed.[15] To include the entire spectrum of opinion, a heterogeneous sample will be used.[17] A national, expert panel will be formed, consisting of about 15 members and including both stomatherapists and people living with an ostomy and considered expert patients. Reporting will follow the Accurate Consensus Reporting Document (ACCORD) checklist.[18]

The expert panel description

Experts will be defined as informed individuals,[19] specialists in their field,[20] or persons possessing substantial knowledge of the topic. Accordingly, the expert panel will consist of nurses specialised in ostomy care (stomatherapists) and expert individuals living with an ostomy. Stomatherapists will be selected based on completion of a 1500-hour post-bachelor specialisation course in stoma care, absence of conflicts of interest related to the research, and a minimum of five years of practice. Individuals living with an ostomy will be chosen in collaboration with the Italian National Federation of Associations of Incontinence and Stomised Patients (FAIS). To guarantee homogeneity the panel will include about 15 participants, as suggested by Delbecq et al.[21] The overall size of the Delphi study will be consistent with Doughty's recommendations.[22]

The recruitment process

Stomatherapists will be recruited through convenience sampling via a mailed invitation letter.[23] Individuals living with an ostomy will be recruited in collaboration with FAIS via an invitation letter distributed by email or via a call.

Research steering group

A research steering committee will be constituted to oversee the study. The committee will prepare and disseminate materials for the Delphi rounds, including investigators with expertise in patient education, ostomy care and the lived experience of ostomy. The committee will not participate in the Delphi ratings; instead, it will supervise and monitor the process. Two researchers will chair the focus group: GV (chair; assistant professor in nursing and PhD nurse) and AP (co-chair; research fellow in nursing and PhD student). Both are nurses and will coordinate the entire Delphi process from the focus group discussion through to the final round.

Confidentiality

The study will ensure confidentiality: although respondents might recognise each other's participation, their evaluations and opinions will remain completely anonymous.[19] Complete anonymity will be guaranteed in the second, subsequent and final rounds; anonymity will not be possible during the focus group discussion.

Rounds

A minimum of three Delphi rounds will be organised; additional rounds may be conducted depending on the percentage of consensus achieved at the end of each round. To ensure quality and clarity, a pilot test of the first-round materials will be performed with both stomatherapists and individuals living with an ostomy.[21,24] The planned duration is six weeks (approximately two weeks per round), and may be extended, if further rounds are required.

First round

The initial round will introduce and discuss preliminary indications for remote patient education derived from a literature review.[25] These indications are general to remote

patient education and not specific to ostomy care, as the literature lacks ostomy-specific guidance. Panel members will join a remotely conducted focus group discussion via Microsoft Teams[26] to explore initial areas of agreement and to present these indications to expert stomatherapists and patients.[27] Two researchers will lead the session: an experienced moderator (GV), who will guide the discussion and ensure adherence to the agenda, and an observer (AP), who will document non-verbal/paraverbal dynamics, record field notes on participant characteristics and behaviors, and support the moderator in achieving the session objectives.[28] The session will begin with participant registration and confirmation of informed consent, followed by a brief overview of the study and ground rules for respectful communication. Discussion will proceed through a pre-specified sequence of literature-derived indications, with the moderator promoting balanced participation. The session will conclude with a summary of key points and prompts for final reflections. The focus group discussion will last approximately 90 minutes.

Second round

The second round will refine and prioritise the indications emerging from the focus group discussion. It aims to gather consensus on the relevance, feasibility, and clarity of preliminary statements derived from Round 1. These statements will address content, format, delivery methods and evaluation strategies for remote educational interventions tailored to people living with an ostomy. To enable efficient, rapid collection of expert opinions with controlled feedback,[29] all Round 1 participants (stomatherapists and expert patients) will rate each statement on a 4-point Likert-type scale (1=strongly disagree; 4=strongly agree) and they will have space to comment, suggest rewording, or propose additions. The questionnaire will be designed to take <30 minutes to complete.[30] In addition, definitions of a set of key terms, such as "remote patient education," "mixed education sessions," "remote education," and "therapeutic patient education", will be presented and evaluated using the same method as the indications, to ensure a shared, expert-validated terminology for subsequent rounds. If the 75% consensus threshold is not achieved in Round 2, additional Delphi rounds will be conducted, iteratively revising and re-rating items, until ≥75% agreement is reached or the panel indicates further convergence is unlikely.

Last round

The final round will finalise expert agreement on the key components of remote education for individuals living with an ostomy. The results and feedback from the previous round will inform its design. The aim will be twofold: to reach a definitive consensus on revised statements that did not meet the agreement threshold in the previous round and to validate the complete set of indications generated across the process, thereby concluding consensus building and ensuring that the final version reflects a shared expert vision.[15] Participants will receive a concise summary of the previous round results, including aggregated ratings and a synthesis of qualitative comments. A streamlined survey will present the final versions of revised statements that previously lacked consensus, together with the complete set of statements already at consensus, for confirmation. Each item will again be rated on the 4-point Likert scale, with optional brief comments. Statements achieving ≥75% agreement will be considered to have reached final consensus. Participants will be explicitly informed that this is the last round and that their responses will shape the final indications for designing and organising remote education for ostomy patients. Quantitative data will determine whether revised items meet the predefined consensus threshold, and qualitative comments will be reviewed to identify any residual ambiguity. However, no further modifications will be planned beyond this round.

Round 2, and any subsequent rounds, including the final round, will be administered as online surveys via Microsoft Forms and distributed to all panelists by email.

Data analysis

Audio from Round 1 will be recorded, transcribed verbatim, and analysed to refine the literature-derived indications and adapt them to ostomy-care educational pathways. Quantitative data from Round 2 (and any subsequent rounds) and from the final round will be analysed using SPSS (Version 29.0.2.0). For each item, descriptive statistics (frequencies and percentages) will be calculated.

Defined agreement

The consensus threshold will be set at 75% agreement, consistent with prior Delphi literature.[31]

Rigor

To maintain methodological rigor, a response rate of at least 70% between rounds will be required.

Reliability

Reliability will be strengthened through several strategies. The use of a focus group in the first round will generate ideas grounded in both professional and lived experience. The same participants will be retained across all three rounds to allow stable comparisons.[32] Anonymity in the second (and any subsequent) round and in the last round will minimise group pressure and social influence.[19] Questionnaires will be pilot-tested to ensure clarity, and controlled feedback from each round will guide the next.[21] Although some authors have questioned the reliability of Delphi studies due to personal and situational biases,[33] this study will follow a straightforward, structured method with consistent panel selection, standardised questionnaire design, and predefined thresholds, thereby reinforcing reliability and overall quality.

Validity

Multiple strategies will support validity. Content and face validity will be addressed by assembling a multidisciplinary panel that includes both expert stomatherapists and patients, thus integrating clinical and experiential knowledge. Conducting Round 1 as a focus group discussion will

enable participants to generate key recommendations directly, ensuring that subsequent rounds reflect real-world perspectives. The iterative structure of the Delphi process, with controlled feedback and item refinement, will allow participants to reassess and clarify their views, enhancing credibility through collective expert judgment. While external validity may be constrained by purposive sampling, national coverage and diversity in geographical representation will mitigate this risk. To improve transparency and confirmability, all steps in design, data collection, analysis and decision-making will be documented in detail.

EXPECTED RESULTS

The study will produce an expert-validated set of indications for remotely delivered therapeutic patient education tailored to people living with an ostomy. Starting from general evidence on remote patient education, these indications will be refined through a multidisciplinary Delphi process that integrates stomatherapists' clinical expertise with the lived experience of expert patients. We expect most items to reach the predefined ≥75% agreement threshold, while areas with limited empirical evidence will be supplemented by clearly signposted expert opinion. The final outputs are expected to specify core educational content; appropriate formats and delivery methods (including criteria for face-to-face, remote, and mixed pathways); and roles and responsibilities across the care team. Minimum standards for equity, privacy, informed consent and data protection will be articulated. In addition, we expect to define a concise minimum data set for routine evaluation, covering outcomes such as self-efficacy, level of self-care, complication alerts and satisfaction, with suggested timing and feasible tools for everyday clinical use.

CONCLUSION

This protocol describes a modified Delphi, designed to generate the first national consensus, potentially the first in Europe, on remote therapeutic patient education for ostomy care. By translating general principles of remote education into ostomy-specific, practice-ready guidance co-produced with clinicians and patients, the study aims to standardise what should be taught, how it should be delivered, who should do it, and how it should be monitored in routine services. The resulting set of indications will offer an immediately usable blueprint for person-centered, equitable and secure remote education, while also providing a common language and measurable outcomes for quality improvement. Although consensus methods do not replace experimental evidence, the outputs of this study are intended to inform feasibility and effectiveness trials, economic evaluations and implementation studies, and can be adapted to other conditions as stronger empirical data on distance education accumulate.

CONFLICT OF INTERESTS

The authors declare no conflict of interest.

ETHIC STATEMENT

This study has been developed in partnership with the Italian National of Association of Incontinence and Ostomy Patients [Federazione Associazioni Incontinenti e Stomizzati] (FAIS). Before initiation, the protocol and all participant-facing materials will be reviewed and formally approved by the FAIS Board (approved on October 29, 2025), as the project is conducted in a shared collaboration with FAIS. The study will adhere to the Declaration of Helsinki and applicable EU/Italian data protection regulations (GDPR/EU 2016/679). Participation will be entirely voluntary; written informed consent will be obtained from all participants; confidentiality and anonymity will be safeguarded; and participants may withdraw at any time without consequence. No procedures beyond usual ethical standards are anticipated, and any protocol amendments will be promptly communicated to FAIS and relevant stakeholders.

FUNDING

The authors received no funding for this research.

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